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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/552,593	11/10/2006	Carsten Momma	117163.00150	2507

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HAHN LOESER & PARKS, LLP
One GOJO Plaza
Suite 300
AKRON, OH 44311-1076

EXAMINER	
HIGGINS, GERARD T	

ART UNIT	PAPER NUMBER
1794	

NOTIFICATION DATE	DELIVERY MODE
05/15/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@hahnlaw.com
akron-docket@hotmail.com

Office Action Summary	Application No.	Applicant(s)	
	10/552,593	MOMMA ET AL.	
	Examiner	Art Unit	
	GERARD T. HIGGINS	1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 November 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *07 October 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/07/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Priority

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Drawings

2. The substitute drawings were received concurrently with the application on 10/07/2005. These drawings are acceptable; however, the Examiner notes that applicants' original drawings can only be found in the documents submitted from the international bureau, and a separate entry is not found with only the original drawings.

Specification

3. The substitute specification filed 10/07/2005 has been entered.

4. The disclosure is objected to because of the following informalities: "silicon carbite" is misspelled at [0010].

Appropriate correction is required.

5. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: in claim 12, applicants are claiming the metals gold,

platinum, and palladium; however, platinum and palladium are not found in the specification.

Claim Objections

6. Applicant is advised that should claim 17 be found allowable, claim 19 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

7. Claims 1 and 6 are objected to because of the following informalities:

   a. In claim 1, "wherein the the marker element" is awkward.

   b. In claim 6, "which forms the metallic carrier structure *and* into which the radiopaque material is placed" is awkward.

   Appropriate correction is required.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 7-10 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a tubular metal carrier structure being ablated and filled with marker elements, does not reasonably provide enablement for "radiopaque material filling a lumen of a tube." The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Case law holds that applicant's specification must be "commensurately enabling [regarding the scope of the claims]" *Ex Parte Kung*, 17 USPQ2d 1545, 1547 (Bd. Pat. App. Inter. 1990). Otherwise **undue experimentation** would be involved in determining how to practice and use applicant's invention. The test for undue experimentation as to whether or not all the articles within the scope of claims 7-10 can be used as claimed and whether claims 7-10 meet the test as stated in *Ex parte Forman*, 230 USPQ 546, 547 (Bd. Pat. App. Inter. 1986) and *In re Wands*, 8 USPQ2d 1400, 1404 (Fed.Cir. 1988). Upon applying this test to claims 7-10, it is believed that undue experimentation **would** be required because:

(a) *The quantity of experimentation necessary* is **great** since claims 7-10 read on "radiopaque material filling a lumen of a tube" while the specification discloses a tubular metal carrier structure being ablated and filled with marker elements [0021] to [0025]; specifically, in the case of what is disclosed in the specification the structures that would be created would have the structure of a wire and not a tube (please see applicants' Figure 3), and it is unclear how one would get the shape of the ablated carrier structure to be tubular.

(b) There is **no** *direction or guidance presented* for making the "radiopaque material filling a lumen of a tube formed from the metal of the carrier structure."

(c) There is an ***absence*** *of working examples* concerning a "radiopaque material filling a lumen of a tube formed from the metal of the carrier structure." In fact, Figures 1-4 seemingly contradict the claimed limitations in the fact that the marker element is formed by ablating the tubular metal carrier structure; hence, creating a wire-like structure, and then filling it with marker elements.

In light of the above factors, it is seen that undue experimentation would be necessary to make and use the invention of claims 7-10. For the purposes of examination, the Examiner will treat these claims as if claim 7 stated that the "marker element comprises radiopaque material filling an aperture of a wire formed from the metal tube of the carrier structure."

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 1-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With regard to claims 2, 13, and 14, in claim 2 applicants state that the carrier structure "is produced by cutting out legs and apertures for marker elements from *a* metal tube." This leads the claim to be indefinite because there is confusion as to how

many metal tubes are present. Should applicants be referring to "*the* metal tube" of claim 1 in the abovementioned claims?

With regard to claims 1-19, the term "relatively radiolucent" in claim 1 is a relative term which renders the claim indefinite. The term "relatively radiolucent" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is unclear to what degree the device must be radiolucent in order to be considered "relatively radiolucent," and hence the claim is indefinite.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 1, 5, 12, and 15-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Kranz et al. (6,312,456).

With regard to claims 1 and 5, Kranz et al. teach the device of Figure 1.

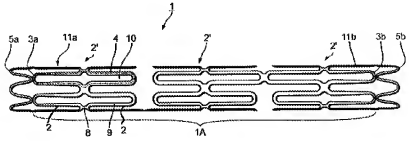


Fig.1

The stent is produced from laser cutting techniques on hollow-cylindrical metal tube rounds (col. 2, lines 38-42 and col. 3, lines 1-3). It may comprise marker elements **5a** and **5b**, which are made of a material that is radiopaque (col. 3, lines 46-58). The marker elements are welded-on threads (col. 3, lines 46-49). The entire device may be covered by a layer of silicon carbide (col. 4, lines 27-30), which comprises a cover layer that completely encloses the radiopaque material. Silicon is a metalloid, which means it is partially a metal, and therefore is a metal or a metal compound.

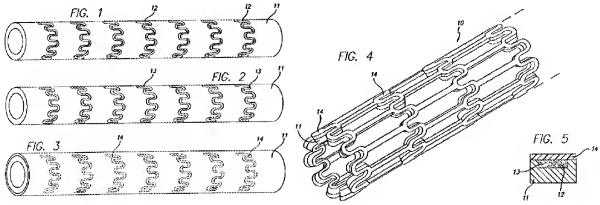
With regard to claim 12, the radiopaque material may comprise gold (col. 2, lines 32-37).

With regard to claims 15-19, it is clear from Figure 1 that the marker element comprises at least part of the carrier structure in the region of a longitudinal end of the stent, and is welded to the rest of the carrier structure.

With regard to claim 20, the stents of Kranz et al. can inherently be placed into a patient; furthermore, Kranz et al. disclose at col. 1, lines 5-10 and 23-28 that these stents are particularly coronary stents, which are used during operations to remove a stenosis.

14. Claims 1-4, 6-16, and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Dang (6,471,721).

With regard to claim 1, Dang discloses the device of Figures 1-5.



The stent comprises a radiolucent carrier structure (col. 3, lines 22-31 and col. 5, lines 12-23). The device may have radiopaque marker elements **13** incorporated therein (col. 5, lines 38-41). Then the device is covered with a cover layer **14**, which may include a metal (col. 5, line 65 to col. 6, line 17).

With regard to claim 2, the grooves **12** comprise the apertures for the marker elements **13**. The marker elements may be attached using laser bonding (col. 5, lines 38-46), which comprises welding; furthermore, the requirement that the marker elements be welded is a product-by-process limitation. It has been held that "even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." Please

see MPEP 2112 and *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

With regard to claims 3, 4, 11, 13, and 14, the device may be comprised of nitinol, which is a nickel-titanium alloy; furthermore, nitinol is inherently a self-expanding carrier that comprises the characteristics of applicants' claims 4 and 14.

With regard to claim 6, Dang discloses at col. 5, lines 14-23 that the materials for the carrier substrate include *inter alia* 316L stainless steel and nitinol. They go on to disclose at col. 6, lines 9-11 that while one preferred material for the covering layer **14** "is 316L stainless steel, other suitable material can be used." The Examiner deems that since 316L stainless steel may be used for the carrier structure and the covering layer that nitinol would be a "suitable material" for the covering layer.

With regard to claims 7-10, 15, and 16, the radiopaque material is incorporated throughout the stent as seen in Figures 1-4. Also the radiopaque material comprises the core of the carrier structure and cover layer (lumen of a tube) as seen in Figure 5. It is clear from the Figures that the radiopaque material comprises at least part of the carrier structure; furthermore, since the radiopaque is incorporated throughout the stent it will necessarily be incorporated in the region of a longitudinal end of the stent. The Examiner has deemed laser bonding to be welding; however, in the case that applicants disagree with that assessment, the requirement that the marker elements be welded is a product-by-process limitation. It has been held that "even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of

production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." Please see MPEP 2112 and *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

With regard to claim 12, Dang discloses at col. 5, lines 41-44 that the radiopaque material may be gold or platinum.

With regard to claim 20, , the stents of Dang can inherently be placed into a patient; furthermore, Dang discloses at col. 1, lines 14-27 that stents are particularly adapted to be implanted into a patient's body.

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

16. Claims 5 and 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dang (6,471,721) as applied to claim 1 in view of Kranz et al. (6,312,456).

With regard to claim 5, Dang discloses all of the limitations of applicants' claim 1 in section 14 above, and it also discloses at col. 6, lines 56-57 that a biocompatibility layer may be added; however, it fails to disclose that the biocompatibility layer contains silicon carbide.

Kranz et al. disclose at col. 2, lines 51-54 that silicon carbide is used as an outer coating layer on the biocompatible stent and counteracts thrombosis formation; further, at col. 4, lines 27-30 that the silicon carbide is used as an outer covering to avoid stenosis.

Since Dang and Kranz et al. are both drawn to stents, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the silicon carbide outer covering layer of Kranz et al. as the biocompatibility layer of Dang. The motivation for doing so has been stated above and includes *inter alia* counteracting thrombosis formation; further, the overcoating of silicon carbide on the device of Dang would produce a stent that had a multilayered covering layer, and as such would still include the nitinol cover (a metal or metal compound) as well as the additional layer of silicon carbide.

With regard to claims 17 and 19, a silicon carbide covering on the entire stent as taught by Kranz et al. would produce a stent that renders obvious applicants' claims 17 and 19 because the stent still has marker elements that form at least part of the carrier structure in the region of a longitudinal end of the stent.

With regard to claim 18, the Examiner has deemed laser bonding to be welding; however, in the case that applicants disagree with that assessment, the requirement that the marker elements be welded is a product-by-process limitation. It has been held that "even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-

process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." Please see MPEP 2112 and *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

Conclusion

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to GERARD T. HIGGINS whose telephone number is (571)270-3467. The examiner can normally be reached on M-F 7:30am-5pm est. (1st Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Callie Shosho can be reached on 571-272-1123. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Gerard T Higgins, Ph.D.
Examiner
Art Unit 1794

/Gerard T Higgins, Ph.D./
Examiner, Art Unit 1794

/Callie E. Shosho/
Supervisory Patent Examiner, Art Unit 1794